BRIEFING PAPER Microbial Commercial Activity Notice J12-0003

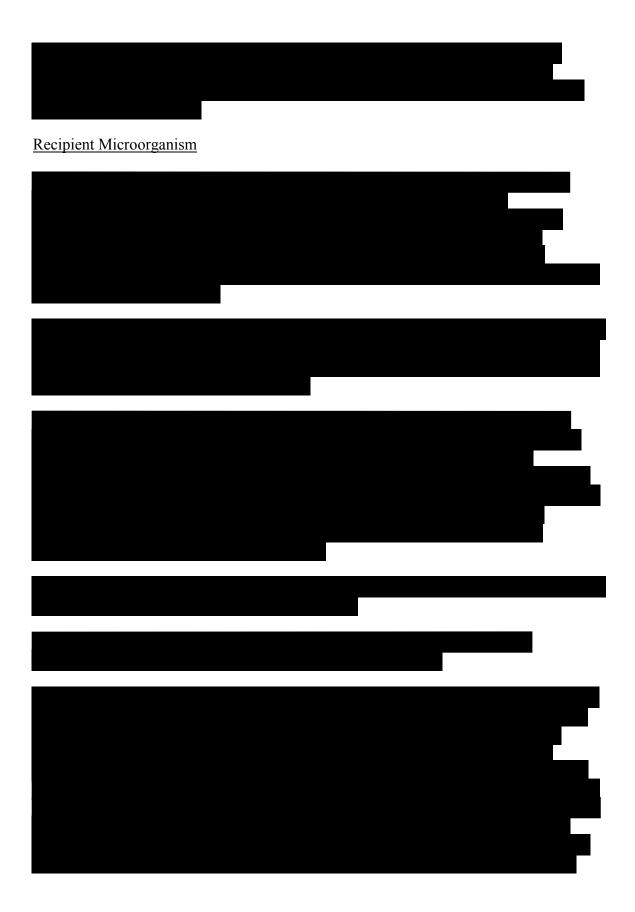
PART I: BACKGROUND DATA

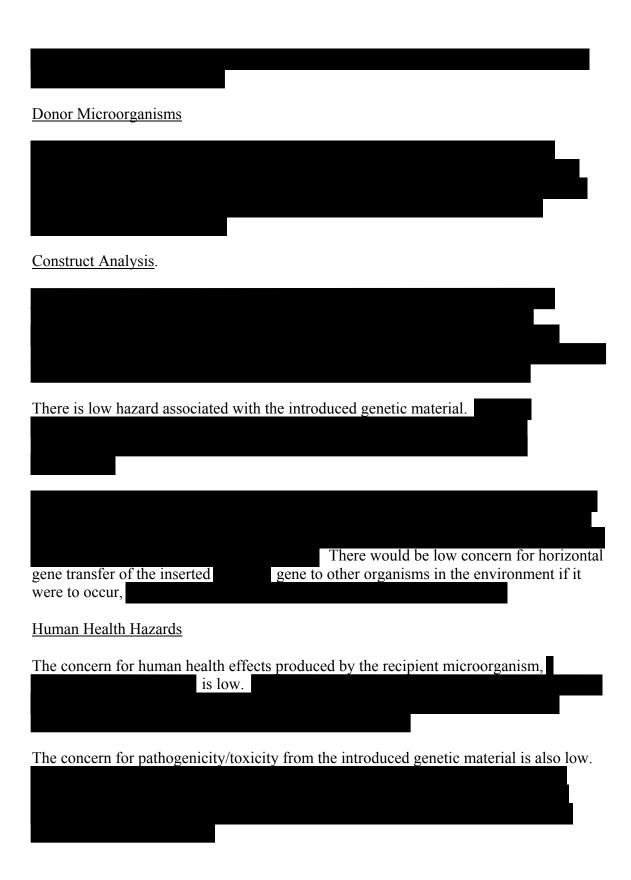
	w Team: Gwen McClung, Mark Segal, Joe Avcin, Ron Ward, Y'Vonne Jones- n, Stephanie Suazo, David Lynch, Audrey Binder
Disposition Date: August 7, 2013	
A. volum	CBI Claims: Everything, including Submitter id; Microbial id; Use; Production e; Process information; All attachments
B.	Submitter: Solazyme, Inc., South San Francisco, CA
C.	Genetically Engineered Microorganism (GEM):
	Donor:
D.	Production Volume (Colony Forming Units)(cfu):
	Year 1: Year 2: Year 3:
E.	Use:
F. The me	Benefits: The genetic engineering adds new properties to the microorganism. odified form of the alga

PART II. RISK SUMMARY

Introduction



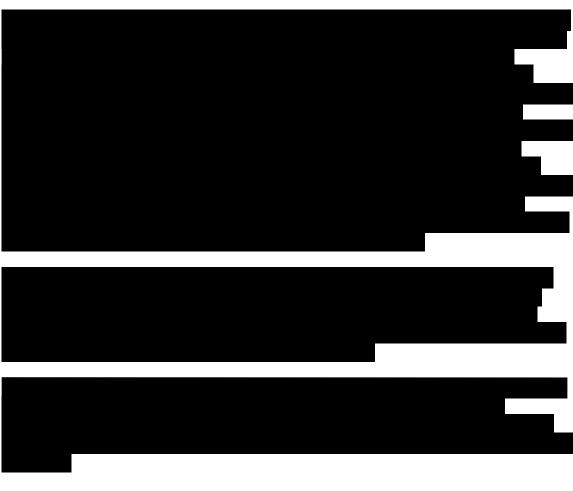




Ecological Hazards



Hazards to Animals



Hazards to Plants



Potential Survival of the Submission Microorganism in the Environment

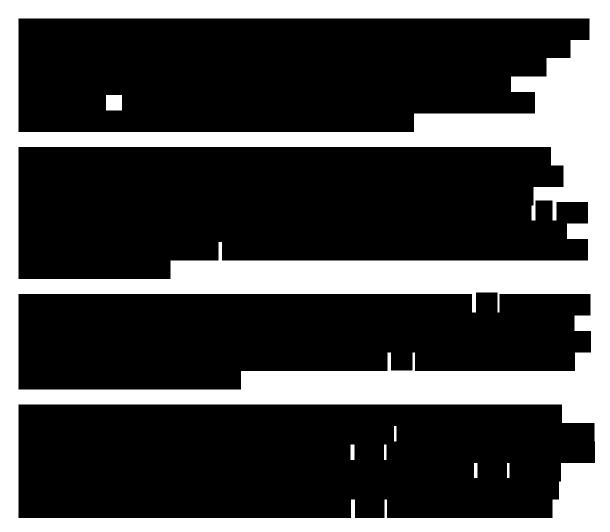
The production strain is expected to survive in the environment if inadvertently released from the facility. It is capable of growth and survival in various environmental media, particularly in wet, muddy areas contaminated with organic matter. Survival and multiplication of would be expected even through wastewater treatment.

PART III: ORGANISM CHARACTERISTICS RELEVANT TO INACTIVATION



PART IV: EXPOSURES AND RELEASES

<u>Description of Operations</u>:



A. Worker Exposure		
Laboratory Activities: Inhalation exposure (bioaerosols): Dermal exposure: Personal Protective Equipment (PPE): gloves, glasses, and lab coats		
Manufacturing and Processing Activities: Inhalation exposure (bioaerosols): Dermal exposure:		
B. Environmental Releases (
<u>Laboratory Activities</u> Laboratory propagation of stock culture (
Potential releases to air are thought to be negligible as no aerosols are expected to be generated. Potential water releases are expected to be negligible		
Manufacturing		
Releases to Air		
2.		
3.		
4.		

5. Drum dryer off-gas: negligible Releases to Water 3. 4. Off-gas treatment system wastewater Releases to Landfill 1. Disposal of spent biomass:

- C. Consumer, General Population, and Environmental Exposure
- 1. <u>Consumer Exposure</u>: The submission microorganism used to produce is inactivated and separated from the so consumer exposure is not expected.

2. General Population Exposure

There is a potential for the general population to be exposed to the alga as a result of releases to air and water from use of the submission microorganism at commercial scale.

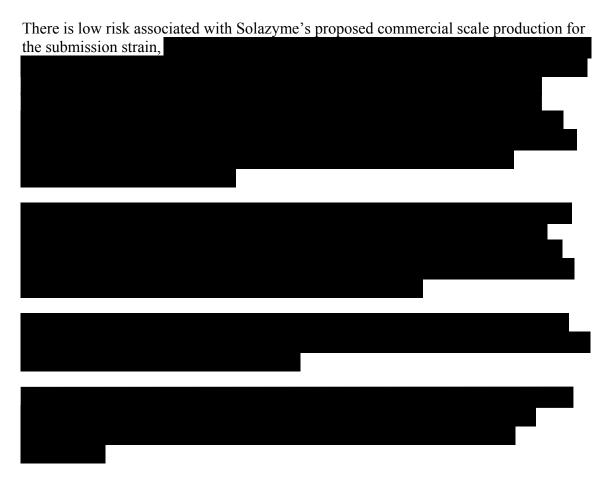
Releases of solids to landfill from inactivated biomass were assumed to be disposed of in accordance with applicable state and/or federal regulations in a lined

landfill with leachate control. General population exposure from landfill disposal of inactivated biomass was, therefore, not assessed.

<u>Inhalation Exposure – </u>

Inhalation exposure, surface water and drinking water exposure are expected to be negligible.

PART IV: RECOMMENDATION AND RATIONALE



Based on the amended information and data received from the submitter, it is recommended that MCAN J12-13 be dropped from further review.